UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE:	**NEW ENGLAND COMPOUNDING PHARMACY CASES**	**Master Docket No. 12-12052-FDS**
This Document Relates To:		
RAYMOND MCDOW, ROSEANNE BROOKS, et. al.,		
	Plaintiffs,	**Civil Action No. 12-12112-FDS**
	v.	
NEW ENGLAND COMPOUNDING PHARMACY, INC., et. al.,		
	Defendants.	

REPLY BRIEF OF ALAUNUS PHARMACEUTICAL, LLC
IN SUPPORT OF ITS MOTION TO DISMISS
(LEAVE TO FILE GRANTED FEBRUARY 8, 2013) (DOC NO. 183)

The Defendant, Alaunus Pharmaceutical, LLC ("Alaunus"), hereby files this reply brief in support of its Motion to Dismiss the Amended Complaint of Plaintiffs Raymond McDow ("McDow") and Roseanne Brooks ("Brooks") for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6). Leave to file this Reply Brief was granted by the Order dated February 8, 2013 (Doc. No. 183).

1. Pleading Standard Applicable to This Case

In their Opposition Memorandum, Plaintiffs suggest that this Court should excuse their failure to comply with the pleading standards under Fed.R.Civ.P. 8(a) in this product liability action because:

> "*Defendants'* actions and inactions have provoked an extraordinary public health catastrophe with dozens killed and hundreds, including plaintiffs herein, seriously

> injured. *Defendants* compounded drugs improperly and their manufacturing and distributing operations were so deficient that they were shut down . . ."

McDow, et. al., Opp. to Alaunus' Mot. to Dismiss, Case No. 12-CV-12052-FDS (Doc. No. 180), p. 5. In other words, the Plaintiffs suggest that this Court should ignore the recent United States Supreme Court decisions in *Twombly* and *Iqbal* because there is a meningitis outbreak affecting hundreds of alleged victims. Plaintiffs' proposition is baseless for a number of reasons.

First, the Plaintiffs offer no authority in support of their proposition that the Court should apply a liberal pleading standard due to the existence of the so-called meningitis outbreak.

Second, the Plaintiffs' proposition contradicts the well-established rule that a complaint fails to meet the minimum standard of pleading under Fed.R.Civ.P. 8(a) where the complaint merely "lumps" multiple defendants together as one entity and does not contain adequate factual allegations to distinguish the conduct of particular defendants. *See Bagheri v. Galligan*, 160 Fed. Appx. 4, 5, 2005 WL 3536555 (1st Cir. 2005) (upholding district court's dismissal of action where the original complaint did not "state clearly which defendant or defendants committed each of the alleged wrongful acts"); *Tolbert v. Clarke*, Civ. Action No. 10-11643, 2011 WL 797372 (D. Mass. 2011) (Zobel, J.) ("lumping" of all of the defendants together is impermissible when it cannot be reasonably inferred that all of the defendants were involved, or it is otherwise not clear to which defendant or defendants the plaintiff is referring).[1]

Third, the liberalization of the pleading standard in complex product liability mass tort litigation is inconsistent with the requirement under Massachusetts law that a plaintiff identifies the manufacturer of the defective product that allegedly caused plaintiff's injuries. As established in

[1] *See also Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2nd Cir. 2001) ("by lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff]'s complaint failed to satisfy [the] minimum standard" of pleading under Fed.R.Civ.P. 8(a)"); *Goren v. New Vision Intern., Inc.*, 156 F.3d 721, 730 (7th Cir. 1998) (affirming dismissal where complaint treated defendants as one by "lumping" them together); *Vanzandt v. OK Dep't Human Serv's.,* 276 Fed. Appx. 843 (10th Cir. 2008) ("to carry their burden, plaintiffs under the *Twombly* standard must do more than generally use the collective term 'defendants.' . . . This is because the purposes of plausibility, notice, and gatekeeping are best served by requiring plaintiffs to directly link an actual individual with the alleged improper conduct").

Alaunus' original memorandum, the Amended Complaint does not allege sufficient facts to identify Alaunus as the manufacturer or distributor of the methylprednisolone acetate injection product that was allegedly used or consumed by the Plaintiffs. None of the materials attached to the Plaintiffs' Opposition Memorandum, which include press releases from the Center for Disease Control and letters from the Plaintiffs' medical providers, even mention Alaunus therein. Consequently, the Amended Complaint should be dismissed for failure to show that Alaunus was the manufacturer or distributor of the allegedly defective methylprednisolone acetate injection product that was used or consumed by the Plaintiffs. *See Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495 (6th Cir. Aug. 23, 2011).[2] Significantly MDL Courts have not hesitated to dismiss numerous cases in those consolidated actions where the plaintiffs' complaints failed to allege sufficient facts to show that the defendant was the manufacturer or distributor of the alleged defective product that caused injury to the plaintiffs. *See In Re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, E.D.KY. Civ. No. 11-MD-2226 (July 31, 2012); *In re Fosamax Products Liability Litigation*, S.D.N.Y. Civ. No. 06-MD-1789, 2010 WL 1654156 (April 9, 2010).

Finally, the Plaintiffs' proposition flies in the face of *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1953 (2009) where the U.S. Supreme Court announced that the plausibility standard articulated in *Bell Atlantic Corp. v. Twombly* applies to *all civil actions*, and the holding in *Twombly* where the Court rejected plaintiff's arguments that it should be allowed to proceed with discovery on the basis that one of the purposes of the plausibility requirement is the avoidance of unnecessary discovery. *Twombly*, 127 S. Ct. at 1966.

[2] *See also Peterson v. Breg*, 2010 U.S. Dist. Lexis 48985 (D. Ariz. April 29, 2010) (dismissing complaint that failed to identify which manufacturers' products were actually used); *Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (dismissing all product liability claims in medical device case under *Twombly-Iqbal* because the pleading asserted only that unknown "defendants" committed actions and failed to state sufficient facts to identify defective product); *Adams v. I-Flow Corp.*, 2010 WL 1339948 (C.D. Cal. Mar. 30, 2010); *Washington v. Wyeth*, Inc., 2010 WL 450351 (W.D. La. Feb. 8, 2010); *Dittman v. DJO, LLC*, 2009 WL 3246128 (D. Colo. Oct. 5, 2009).

2. Legal Conclusions Versus Factual Allegations

Notwithstanding the bald assertions in their Amended Complaint, Plaintiffs insist that they have asserted sufficient factual allegations against Alaunus in support of their various claims because they alleged in their Amended Complaint that "Defendant Alaunus ***holds itself out*** as a pharmaceutical development company and ***acts as a distributor of*** pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose." *McDow, et. al., Opp. to Alaunus' Mot. to Dismiss,* Case No. 12-CV-12052-FDS (Doc. No. 180), p. 7, citing *Pl. Compl.* at ¶ 20. By making this contention, Plaintiffs suggest that the allegations in paragraph 20 of the Amended Complaint must be deemed as true on a 12(b)(6) motion to dismiss because they are *factual* as opposed to *legal* conclusions. Plaintiffs' suggestion has no merit.

In *The Dartmouth Review v. Dartmouth College*, the First Circuit stated that:

> "We are cognizant that the line between "facts" and "conclusions" is often blurred. But, there are some general parameters. Most often, facts are susceptible to objective verification. Conclusions, on the other hand, are empirically unverifiable in the usual case. They represent the pleader's reactions to, sometimes called "inferences from," the underlying facts. It is only when such conclusions are logically compelled, or at least supported, by the stated facts, that is, when the suggested inference rises to what experience indicates is an acceptable level of probability, that "conclusions" become "facts" for pleading purposes."

889 F.2d 13, 16 (1st Cir. 1989).[3] Implicitly following this rationale, courts have similarly held that the determination as to whether an entity exercised "control" over a worker, whether an officer was "acting under color of law," and whether an employer's termination of an employee was "in retaliation" for the employee's protected conduct are conclusory unless supported by independent factual allegations because the truth of those assertions are not susceptible of objective verification and depend upon inferences from underlying facts or application of law to the facts of the case.

[3]Thus, the First Circuit has held that terms like "conspiracy" and "agreement" are conclusory unless supported by independent factual allegations from which an inference may be drawn as to the existence of a conspiracy or agreement exists. *See DM Research v. College of American Pathologists*, 170 F. 3d 53, 55 (1st Cir. 1999).

See Doe I v. Wal-Mart Stores, Inc., 572 F.3d 677, 683 (9th Cir. 2009) (holding allegation that Wal-Mart exercised "control" over day-to-day employment so as to constitute a joint employer was conclusory).[4]

Similar to assertions that a master had "control" over an alleged servant and that an officer was "acting under color of law," the assertions that Alaunus "holds itself out" as a pharmaceutical developer and "acts as a distributor" of the products manufactured by NECC and Ameridose are not purely factual. The ascertainment of the truth of those statements depends upon inferences from underlying facts. For example, the determination as to whether a company "held itself out" as a licensed home improvement contractor may depend on whether the defendant in fact made a statement on its website, in marketing materials, or in a written agreement that it was a licensed home improvement contractor. Similarly, the determination as to whether a company "acts as a distributor" of products for a manufacturer depends on facts such as whether a distribution agreement existed between the parties, whether the alleged distributor's logo or trademark was printed on product labeling, and whether the alleged distributor engaged in a course of selling the manufacturer's product on a wholesale basis and shipping those products to various retailers. Additionally, the determination as to whether Alaunus "acts as a distributor" is a mixed question of fact and law because the word "distributor" is a term that has a specific meaning under applicable state statutes or common law.[5] Given that Plaintiffs' assertions that Alaunus "holds itself out" as a

[4] *See also Claudio v. Sawyer*, 675 F. Supp. 2d 403, 407–10 (S.D.N.Y. 2009) (holding allegation that off-duty officer was "acting under color of law" was conclusory in the absence of factual showing that officer was acting in capacity as police officer); *Delgado-O'Neil v. City of Minneapolis*, No. 08-4924 (MJD/JJK), 2010 WL 330322, at *10–11 (D. Minn. Jan. 20, 2010) (finding allegation that defendant took several adverse employment actions "in retaliation" for plaintiff's protected conduct were conclusory).

[5] For example, in *Albertson's Inc. v. Department of Business Regulation*, 184 Mont. 12, 601 P.2d 43 (Mont. 1979), the Supreme Court of Montana interpreted and applied the statutory definition of the term "distributor" under Montana's Milk Control Act and held that the plaintiff retail grocery store was not a "distributor" under the Act because it purchases milk from a licensed dealer for resale over the counter at retail. *See also Z & S Distributors, Inc. v. Schoenling Brewing Co.*, 2001 WL 1516935 (Ohio App. First Dist. 2001) (comparing definitions of "distributor" and "manufacturer" under Ohio's Franchise Act and holding that plaintiff was not a "distributor" under the Franchise Act because the legislature intended the term to apply only to in-state distributors and the plaintiff's operations were all out

pharmaceutical developer and "acts as a distributor" of the products manufactured by NECC and Ameridose is not supported by any independent factual allegations in the Amended Complaint, those statements are "bare assertions" which should be disregarded by the Court in deciding the Motion to Dismiss.

3. The Failure to Warn Claim

In an attempt to show that the Amended Complaint alleges a plausible warning defect claim, Plaintiffs contend that the Defendants are not "immunized" from liability on a failure to warn theory under the Learned Intermediary Rule by virtue of the existence of labeling that accompanied the product which warned of possible adverse reactions including the signs and symptoms allegedly suffered by the Plaintiffs. In support of this contention, Plaintiffs assert that they were not warned that there was a "leaky boiler" or other conditions relative to the facilities and equipment on the premises where the methylprednisolone acetate compounds were allegedly made. *McDow, et. al., Opp. to Alaunus' Mot. to Dismiss,* Case No. 12-CV-12052-FDS (Doc. No. 180), p. 7, citing *Pl. Compl.* at ¶ 5 -8. There are numerous problems with this contention.

As an initial matter, the failure to warn claim that is described in the opposition papers is qualitatively different from failure to warn claim articulated in the Amended Complaint. The Amended Complaint articulates a failure to warn claim based on alleged inadequacies in the warnings concerning the risks of using the medication that was provided in the labeling that accompanied the product.[6] On the other hand, the duty to warn claim that is articulated in the Plaintiffs' Opposition Memorandum is based on an alleged failure to warn or to disclose to the Plaintiffs that there was a "leaky boiler" and other issues purportedly affecting the premises where

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of state); *Ohio State Bd. of Pharmacy v. Poppe*, 48 Ohio App.3d 222, 549 N.E.2d 541 (Ohio App. 1988) (stating that "naturally, in order to determine whether a person qualifies as a 'wholesale distributor of dangerous drugs,' the definition of that term must be consulted" under applicable state statute).

[6] *See Pl. Compl.* at ¶ 56 – 57 (stating that Defendants had a duty to warn of the risks attendant to injections of methylprednisolone acetate and that warnings in effect "were both substantially and graphically wholly inadequate" to alert of the "actual risks associated with these drugs, which was known, or should have been known to Defendants").

the pharmaceutical compounds were made. Plaintiffs' failure to warn claim is a moving target which fails to state a claim under either theory.

The Amended Complaint fails to state a plausible failure to warn claim. The Amended Complaint baldly asserts that the warnings in effect "were both substantially and graphically wholly inadequate" to alert of the "actual risks associated with these drugs, which was known, or should have been known to Defendants." Given that the pleading does not contain any allegations as to what the warning was and how it was inadequate, the failure to warn claim is merely a formulaic recitation of the elements of the cause of action which does not satisfy the notice pleading standards of Rule 8(a). *See Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. Appx. 597 (11th Cir. July 29, 2008) (warning defect claims dismissed due to failure to plead facts concerning how the warning to the prescribing physician was inadequate).[7]

The failure to warn claim that is articulated in Plaintiffs' Opposition Memorandum similarly fails to pass muster. A distributor may have a duty to warn of risks that are known or readily ascertainable. As set forth above, the Amended Complaint does not show that Alaunus had any such duty because it does not allege sufficient facts to support the conclusion that Alaunus was the distributor of NECC and Ameridose products. Additionally, assuming for the purposes of a motion to dismiss only that the premises where the product was allegedly compounded was in the condition described in the Amended Complaint, *the fact that the premises was in the described condition*, without more, does not sustain a reasonable inference *that the steroid compound was in fact contaminated*. Consequently, even if Alaunus was a "distributor" of NECC and Ameridose products (which it is not), the failure to warn claim that is described in Plaintiffs' Opposition Memorandum is not plausible because it does not show that Alaunus knew or readily could have

[7] *See also Reed v. Pfizer Inc.*, 2012 WL 859729 (E.D.N.Y. March 14, 2012) (warning claims dismissed due to failure to plead what the warning was or how it was inadequate, particularly since the precise risk was in fact warned of, and design claims dismissed due to failure to plead any alternative design); *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp.2d 787 (S.D. Ohio July 23, 2009) (design and manufacturing claims against drug manufacturer dismissed due to formulaic pleadings of defect and causation).

ascertained that the steroid injection product that was allegedly compounded by NECC or Ameridose was contaminated with a fungal agent.

4. Medical Monitoring Claim

Plaintiffs have failed to allege sufficient facts to demonstrate a plausible right to recovery for medical monitoring under *Donovan v. Phillip Morris USA, Inc.*, 455 Mass. 215, 226 (2009).[8] While the press releases and studies from the CDC that have been attached to Plaintiff's Opposition Memorandum may cure some of the deficiencies in the Amended Complaint as to the allegation of facts necessary to make out some of the elements of a medical monitoring claim, it does not sustain Plaintiffs' burden of showing the core elements of such cause of action. *Alaunus* cannot be held liable for the costs of such medical monitoring because the Amended Complaint, as pled, does not meet the first three elements of the cause of action as established by *Donovan* since the pleading does not show that *Alaunus* negligently manufactured or distributed any products, or that any such negligence caused the Plaintiffs to become exposed to fungal contamination. Nor does the Amended Complaint contain sufficient allegations that the Plaintiffs have had subcellular changes showing the increased risk of contracting spinal meningitis, particularly because the signs and symptoms experienced by the lead Plaintiffs are wholly consistent with *side effects* of *non-contaminated, brand name* methylprednisolone acetate products. Given that the documents attached to Plaintiffs' Opposition Memorandum do not cure these deficiencies as to the right of action against Alaunus, Plaintiffs have failed to "nudge" the medical monitoring claims across the line from conceivable to plausible.

[8] In *Donovan*, the Supreme Judicial Court of Massachusetts stated that a plaintiff may recover medical expenses for diagnostic tests needed to monitor medically a person who has been substantially exposed to a toxic substance that has created physiological changes indicating a substantial increase in risk that the person will contract a serious illness or disease where the plaintiff alleges and proves that: (1) the defendant's negligence (2) caused (3) the plaintiff to become exposed to a hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint. 455 Mass. at 226.

5. Class Certification

In addition to Plaintiffs' failure to state a plausible medical monitoring claim against Alaunus, their claim for certification of a nation-wide class action also fails.

Rule 23(c)(1) of the Federal Rules of Civil Procedure provides that "[a]s soon as practicable after the commencement of an action brought as a class action, the court shall determine by order whether it is to be so maintained." The language of this rule is tailored to invite a defendant to attack the class action allegations of a complaint even before the plaintiff has filed its motion for certification. *Brown v. Milwaukee Spring Co.*, 82 F.R.D. 103 (E.D.Wis. 1979). Accordingly, the defendant is afforded the opportunity to illustrate to the court that the class allegations should be dismissed as a matter of law for failure to state a class claim that can sustain the fundamental requirements of Rule 23. *See In re American Medical Systems, Inc.*, 75 F.3d 1069, 1079 (6th Cir. 1996) ("a class is not maintainable as a class action by virtue of its designation as such in the pleadings"); *Reilly v. Gould Inc.*, 965 F.Supp. 588, 594 (M.D.Pa. 1997) (a court "may address the substance or merits of the plaintiff 's case [in a motion to dismiss] in order to determine whether the requirements of Rule 23(a) have in fact been met").

A district court must conduct a rigorous analysis of the prerequisites established by Rule 23 before certifying a class. *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 161 (1982). To obtain class certification, the plaintiff must establish the four elements of Rule 23(a) and one of several elements of Rule 23(b). *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 614 (1997). The Rule 23(a) elements are (1) numerosity, (2) commonality, (3) typicality, and (4) adequacy of representation. *Id.* at 613. Rule 23(b)(3) requires, in pertinent part, that "the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Given that the Amended Complaint fails to meet the

predominance requirement in Rule 23(b)(3), the Plaintiffs' class action claim should be dismissed pursuant to Fed.R.Civ.P. 12(b)(6). *See Muttart v. American Mortgage & Guaranty Co.,* 1998 Del. Super. LEXIS 30, 1998 Westlaw 110067 (dismissing class certification claim in toxic tort suit).

At the outset, it should be noted that mass tort cases tend to "present 'significant questions, not only of damages but of liability and defenses of liability, ... affecting the individuals in different ways.'" *Amchem Prods., Inc. v. Windsor,* 521 U.S. 591, 625 (1997) (alteration in original) (quoting the Adv. Comm. Notes, 28 U.S.C. App., p. 697); *Blyden v. Mancusi*, 186 F.3d 252, 270 (2d Cir. 1999) (noting that the analysis in *Amchem* "sharply curtailed the ability to certify a class action pursuant to Rule 23(b)(3) in the mass tort context"). The notion that certification is generally improper in mass tort cases has a particular emphasis in products liability actions where, as here, characteristically "no single happening or accident occurs to cause similar types of physical harm or property damage. . . no one set of operative facts establishes liability. . . no single proximate cause applies equally to each potential class member and each defendant . . . [and] furthermore, the alleged tortfeasor's affirmative defenses (such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations) may depend on facts peculiar to each plaintiff's case." *In re American Medical Systems, Inc.*, 75 F.3d 1069, 1084-85 (6th Cir. 1996) (decertifying class of persons claiming injury from implantation of prosthesis). Thus, many Courts of Appeals have affirmed decertification decisions noting the difficulties posed by class-treatment of mass products liability cases. *See Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1304 (7th Cir. 1995) (noting criticism of the use of class actions in mass tort cases and decertifying class of hemophiliacs alleged to have contracted HIV following infusion of defendants' blood products).[9]

[9] *See also Castano v. Am. Tobacco Co.*, 84 F.3d 734, 746 (5th Cir.1996)(decertifying class of tobacco smokers); *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1233 (9th Cir. 1996) (decertifying pharmaceutical drug class); *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 142 (3rd Cir. 1998) (upholding decertification of class of smokers and noting that individualized issues tend to predominate in mass tort accidents that do not arise out of a single accident); *In re*

In addition to the lack of predominance of issues of fact common to the members of the putative class in mass product liability actions, those actions are also characterized by a lack of predominance of issues of law. A federal court considering nationwide class certification "must apply an individualized choice of law analysis to each plaintiff's claims." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 823 (1985), aff'd sub nom., *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). There is a true conflict of law as to whether the members of a nation-wide class have a cause of action for medical monitoring because several states recognize a claim for medical monitoring absent any present physical injury,[10] several states do *not* recognize a claim for medical monitoring absent some present physical injury,[11] several states have been confronted with the question as to whether to adopt a cause of action for medical monitoring but have declined to address the question or observed that the issue is unresolved,[12] and some states like Alaska, Hawaii, and Idaho have yet to even confront the question in a published decision. Except for those putative class members who reside in Massachusetts or those members who reside in states that allow claims for medical monitoring upon a showing of exposure to a hazardous substance that

Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 66, n. 35 (S.D.N.Y. 2002) (rejecting class certification regarding recalled diabetes drug citing fifteen other district court decisions denying certification of medical products liability class actions).

[10] *See e.g. Burns v. Jaquays Mining Corp.*, 752 P.2d 28 (Ariz. Ct. App. 1987); *California Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795 (Cal. 1993); *Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468 (D. Colo. 1991).

[11] *Hinton ex rel. Hinton v. Monsanto Co.*, 813 So. 2d 827 (Ala. 2001); *Mergenthaler v. Asbestos Corp.*, 480 A.2d 647 (Del. 1984); *Baker v. Westinghouse Elec. Corp.*, 70 F.3d 951 (7th Cir. 1995) (applying Indiana law); *Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515 (D. Kan. 1995); *Kentucky Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849 (Ky. 2002); *Henry v. Dow Chem. Co.*, 701 N.W.2d 684 (Mich. 2005); *Bryson v. Pillsbury Co.*, 573 N.W.2d 718 (Minn. Ct. App. 1998); *Thomas v. FAG Bearings Corp.*, 846 F. Supp. 1400 (W.D. Mo. 1994); *Trimble v. Asarco, Inc.*, 232 F.3d 946 (8th Cir. 2000) (apply Nebraska law), abrogated on procedural grounds by *Exxon Mobil Corp. v. Allapattah Servs. Inc.*, 125 S. Ct. 2611 (2005); *Nevada Badillo v. Am. Brands, Inc.*, 16 P.3d 435 (Nev. 2001); *Carroll v. Litton Sys., Inc.*, No. B-C-88-253, 1990 WL 312969 (W.D.N.C. Oct. 29, 1990); *Rosmer v. Pfizer, Inc.*, No. CIV.A. 9:99-2280- 18RB, 2001 WL 34010613 (D.S.C. Mar. 20, 2001); *Norwood v. Raytheon Co.*, No. EP-04-CA-127- PRM, 2006 WL 267335 (W.D. Tex. Jan. 17, 2006); *Ball v. Joy Techs., Inc.*, 958 F.2d 36 (4th Cir. 1991) (applying Virginia law), cert. denied, 502 U.S. 1033 (1992); *Purjet v. Hess Oil Virgin Islands Corp.*, Civ. No. 1985/284, 1986 WL 1200 (V.I. Jan. 8, 1996); *Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601 (W.D. Wash. 2001).

[12] *Baker v. Wyeth-Ayerst Labs. Div.*, 992 S.W.2d 797 (Ark. 1999); *Martin v. Shell Oil Co.*, 180 F. Supp. 2d 313 (D. Conn. 2002) (unresolved); *Philip Morris Inc. v. Angeletti*, 752 A.2d 200 (Md. 2000); *Barreras Ruiz v. Am. Tobacco Co.*, 180 F.R.D. 194 (D.P.R. 1998); *Craft v. Vanderbilt Univ.*, 174 F.R.D. 396 (M.D. Tenn. 1996).

produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury, there is a true conflict of law on the issue as to whether each individual member of the putative class may recover the costs of medical monitoring.

Under Massachusetts' choice-of-law rules, tort claims are governed by the law of the state in which the injury occurred, unless another state has a more significant relationship to the underlying cause of action. *Bergin v. Dartmouth Pharm., Inc.*, 326 F. Supp. 2d 179, 183 (D. Mass. 2004), citing *Dunfey v. Roger Williams Univ.*, 824 F. Supp.18, 21 (D. Mass. 1993). For the purpose of this analysis with respect to each member of the putative class, the place where the injury occurred is where the member allegedly received the steroid injections since that is "the place where the last event necessary to make an actor liable for an alleged tort takes place." *See Cohen v. McDonnell Douglas Corp.*, 389 Mass. 327, 334 (1983). While Massachusetts has an interest in regulating businesses that operate within its borders, it is significant that there are very few putative class members who are residents of Massachusetts. Accordingly, Massachusetts' interest in regulating business' to deter the distribution of unsafe products within its borders is outweighed by the interests of the states where each of the individual members of the putative class reside in providing their residents with pharmaceutical products by creating more predictable standards of care for drug companies that would encourage the drug companies to market their products in those states. *See Rowe v. Hoffmann-La Roche Inc.*, 917 A.2d 767 (N.J. 2007) (affirming trial court's decision that Michigan substantive law applied in products liability action by resident of Michigan who sustained an alleged injury in Michigan against New Jersey manufacturer and that the defendant-manufacturer was therefore immune from liability under Michigan statute because, after comparing the different state interests under New Jersey's governmental interest choice of law rules, Michigan's interest in providing its citizens with affordable medications prevailed over New Jersey's interest in regulating its manufacturers).

In sum, there is a true conflict of laws and Massachusetts' choice of law rules dictates applying the substantive law pertaining to medical monitoring where each individual member of the putative class resides. Some putative class members may have a right to recover medical monitoring costs while many others will not. Due to the lack of predominance of common issues of law pertaining to the question as to whether individual class members have a cause of action to recover medical monitoring costs, class certification is inappropriate. *See In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293 (7th Cir. March 16, 1995) (nationwide class certification reversed on mandamus for lack of manageability due to multiple state laws).[13] Indeed, numerous courts that have been confronted with putative nation-wide medical monitoring classes have denied certification on the basis that the claim lacks predominance and manageability due to multiple, conflicting state laws as to whether an individual plaintiff has a cause of action for medical monitoring in their resident jurisdiction. *See e.g., Zinser v. Accufix Research Institute, Inc.*, 253 F.3d 1180 (9th Cir. June 15, 2001) (denial of nationwide class certification affirmed for lack of predominance due to multiple state laws and plaintiff-specific variations; no medical monitoring subclass).[14]

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[13] *See also Raye v. Medtronic Corp.*, 696 F. Supp. 1273 (D. Minn. Oct. 19, 1988) (nationwide class certification denied for lack of predominance due to multiple state laws and plaintiff-specific variations); *Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667 (N.D. Ohio Feb. 27, 1995) (statewide class certification denied in DES case due to lack of commonality because of multiple defendants, multiple state laws, and plaintiff-specific variations); *Fisher v. Bristol-Myers Squibb Co.*, 181 F.R.D. 365 (N.D. Ill. May 28, 1998) (nationwide class certification denied for lack of predominance due to plaintiff-specific variations and lack of manageability due to multiple state laws); *Neely v. Ethicon, Inc.*, 2001 WL 1090204 (E.D. Tex. Aug. 15, 2001) (nationwide class certification denied for lack of predominance due to multiple state laws and plaintiff-specific variations).

[14] *See also Rader v. Teva Parenteral Medicines, Inc.*, 276 F.R.D. 524 (D. Nev. Oct. 5, 2011) (propofol medical monitoring class action of all persons allegedly exposed to pathogens at particular clinic denied); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002) (denying certification of medical monitoring class action due to lack of commonality of legal issues); *In Re Prempro Products Liability Litigation*, 230 F.R.D. 555 (E.D. Ark. 2005) (denying certification of medical monitoring class action due to lack of commonality of legal issues); *In re Propulsid Products Liability Litigation*, 208 F.R.D. 133 (E.D. La. June 4, 2002) (nationwide medical monitoring class certification denied for lack of manageability due to multiple state laws); *Perez v. Metabolife International, Inc.*, 218 F.R.D. 262 (S.D. Fla. Sept. 26, 2003) (nationwide and statewide medical monitoring class certification denied in ephedra litigation due to plaintiff-specific variations and multiple state laws); *Zehel-Miller v. AstraZenaca Pharmaceuticals, L.P.*, 223 F.R.D. 659 (M.D. Fla. Aug. 25, 2004) (nationwide class certification denied; no medical monitoring class due to multiple state laws and plaintiff-specific variations defeating cohesiveness).

6. Conclusion

As Alaunus established in its original memorandum in support of its Motion to Dismiss, the Amended Complaint fails to state a plausible claim for relief under any theory of liability against Alaunus including the claim for class certification. Due to the massive scope of expected discovery in this mass products liability action, Plaintiffs are not entitled to conduct any discovery to cure the defects in their pleading. *See Twombly*, 127 S. Ct. at 1966; *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) ("something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with `a largely groundless claim' be allowed to `take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value"). Consequently, the Court should dismiss the Amended Complaint in its entirety, or at the very least as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6).

Dated: February 8, 2013

Respectfully submitted,
Defendant Alaunus Pharmaceutical, LLC
By its Attorneys,

/s/ Ryan Ciporkin

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CERTIFICATE OF SERVICE

I, Ryan Ciporkin, hereby certify that, on this 8th day of February 2013, the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Ryan Ciporkin

Ryan Ciporkin